

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION**

SARA ALI and DANIEL ALI,)
Plaintiffs,)
v.) Case No.: 1:12-cv-00115-GBL-TRJ
ALLERGAN USA, INC.,)
Defendant.)

DEFENDANT ALLERGAN'S ORIGINAL ANSWER

Defendant Allergan USA, Inc. (“Allergan” or “Defendant”) files this Original Answer and Defenses to the Verified Complaint (“Complaint”) of Plaintiffs Sara Ali and Daniel Ali (“Plaintiffs”) Sara Ali and Daniel Ali (“Plaintiffs”).

THE PARTIES¹

1. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint.
2. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint.
3. Paragraph 3 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant admits the allegations contained in Paragraph 3 of the Complaint.
4. Defendant admits the allegations contained in Paragraph 4.

¹ For the Court’s convenience, Allergan will use the same headings as Plaintiffs used in their Complaint to provide its answers and defenses. In doing so, Allergan does not intend to waive any defensive theory or agree or agree that Plaintiffs’ headings are accurate, appropriate, or substantiated.

5. Paragraph 5 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant admits that it conducts business in New York.

6. Paragraph 6 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant admits that it derives income from goods used or consumed in New York.

7. Paragraph 7 of the Complaint states conclusions of law for which no answer is required. Further, the terms “expected or should have expected its business activities to have consequences” is vague and ambiguous. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 7 of the Complaint.

8. In response to Paragraph 8 of the Complaint, Defendant admits that it designs, manufactures, markets, sells, and distributes the LAP-BAND® Adjustable Gastric Banding System (“LAP-BAND®”) in the United States for use by licensed physicians, for particular indications, in accordance with the FDA-approved and/or other regulatory approved information and subject to the precautions, warnings, contraindications and other information contained therein. Defendant denies the remaining allegations of Paragraph 8 of the Complaint to the extent they are deemed factual.

[Paragraphs 9-14 were omitted from the Complaint.]

15. The allegations of Paragraph 15 do not require an answer.

16. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16 of the Complaint.

17. Paragraph 17 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 17 of the Complaint.

FACTUAL BACKGROUND

18. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18 of the Complaint.

19. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19 of the Complaint.

20. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20 of the Complaint.

21. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 21 of the Complaint.

22. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22 of the Complaint.

23. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 23 of the Complaint.

24. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 24 of the Complaint.

AS FOR THE FIRST CAUSE OF ACTION AGAINST DEFENDANT ALLERGAN USA, INC. (FRAUD BY NEGLIGENT MISREPRESENTATION)

25. Paragraph 25 of the Complaint does not require a response.

26. Paragraph 26 of the Complaint, including subparts (a)-(d), states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 26 of the Complaint, including subparts.

27. Paragraph 27 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 27 of the Complaint.

28. Paragraph 28 of the Complaint states conclusions of law for which no answer is required. Defendant admits that it complied with all applicable laws and regulations at all times and denies that its LAP-BAND® device failed to meet the guidelines established by the U.S. Food and Drug Administration (“FDA”). FDA’s “conditions of approval” referred to in Paragraph 28 speak for themselves. Defendant denies the allegations of Paragraph 28 to the extent they are taken out of context.

29. Paragraph 29 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 29 of the Complaint.

30. Paragraph 30 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 30 of the Complaint.

31. Paragraph 31 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 31 of the Complaint.

32. Paragraph 32 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 32 of the Complaint.

33. Paragraph 33 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 33 of the Complaint.

34. Paragraph 34 of the Complaint states conclusions of law for which no answer is required. Defendant is without knowledge or information sufficient to form a belief as to the truth of the statement regarding Plaintiffs' reliance in Paragraph 34 of the Complaint. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 34 of the Complaint.

35. Paragraph 35 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 35 of the Complaint.

36. Paragraph 36 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 36 of the Complaint.

37. Paragraph 37 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 37 of the Complaint.

38. Paragraph 38 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 38 of the Complaint.

**AS FOR THE SECOND CAUSE OF ACTION AGAINST DEFENDANT
ALLERGAN USA, INC. (FRAUD BY NONDISCLOSURE)**

39. Paragraph 39 does not require a response.

40. Paragraph 40 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 40 of the Complaint.

41. Paragraph 41 of the Complaint states conclusions of law for which no answer is required. Defendant is without knowledge or information sufficient to form a belief as to the truth of the statement regarding Plaintiffs' reliance in Paragraph 41 of the Complaint. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 41 of the Complaint.

42. Paragraph 42 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 42 of the Complaint.

43. Paragraph 43 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 43 of the Complaint.

44. Paragraph 44 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 44 of the Complaint.

**AS FOR THE THIRD CAUSE OF ACTION AGAINST DEFENDANT
ALLERGAN USA, INC. (NEGLIGENCE)**

45. Paragraph 45 requires no response.

46. Paragraph 46 of the Complaint states conclusions of law for which no answer is required. The actions of the Gastroenterology and Urology Devices Panel speak for themselves. Defendant denies the allegations of Paragraph 46 to the extent they are taken out of context.

47. Paragraph 47 of the Complaint states conclusions of law for which no answer is required. The FDA actions and communications referred to in Paragraph 47 speak for themselves. Defendant denies the allegations of Paragraph 47 to the extent they are taken out of context

48. Paragraph 48 of the Complaint states conclusions of law for which no answer is required. Defendant admits that it complied with all applicable laws and regulations at all times and denies that its LAP-BAND® device failed to meet FDA guidelines and requirements.

49. Paragraph 49 of the Complaint states conclusions of law for which no answer is required. Defendant admits that it complied with all applicable laws and regulations at all times and denies that its LAP-BAND® device failed to meet FDA guidelines and requirements.

50. Paragraph 50 of the Complaint states conclusions of law for which no answer is required. Defendant admits that it complied with all applicable laws and regulations at all times and denies that its LAP-BAND® device failed to meet FDA guidelines and requirements.

51. Paragraph 51 of the Complaint states conclusions of law for which no answer is required. Defendant admits that it complied with all applicable laws and regulations at all times and denies that its LAP-BAND® device failed to meet FDA guidelines and requirements.

52. Paragraph 52 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 52 of the Complaint.

53. Paragraph 53 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 53 of the Complaint.

54. Paragraph 54 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 54 of the Complaint.

55. Paragraph 55 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 55 of the Complaint.

**AS FOR THE FOURTH CAUSE OF ACTION AGAINST ALLERGAN USA, INC.
(LOSS OF CONSORTIUM)**

56. Paragraph 56 requires no response.

57. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 57 of the Complaint.

58. Paragraph 58 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 58 of the Complaint.

59. Paragraph 59 of the Complaint states conclusions of law for which no answer is required. To the extent the allegations are deemed factual, Defendant denies the allegations in Paragraph 59 of the Complaint.

RELIEF REQUESTED

Answering the "WHEREFORE" paragraph of the Complaint, Allergan denies that Plaintiffs are entitled to any part of the judgment requested or damages sought and deny that it is liable to Plaintiffs in any manner or amount.

AFFIRMATIVE DEFENSES

1. Defendant denies the material allegations of the Complaint, both separately and severally, and demands strict proof thereof.

2. Defendant asserts that some or all of the Counts in the Complaint fail to state a claim against them for which relief can be granted.

3. The product at issue complied in all material respects with all applicable statutes and regulations, including all requirements under the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k, 42 U.S.C. § 262, and regulations issued under such provisions. Defendant has previously filed a *Motion to Dismiss or Alternatively Motion to Require Repleading of Fraud Claims* (see Docket ## 10-11) (“Motion to Dismiss”) setting out in more detail the bases for its preemption defense in this regard, which is incorporated by reference.

4. Plaintiffs’ claims are preempted, modified, and/or limited, in whole or in part, by state and/or federal law. Defendant has previously filed a Motion to Dismiss setting out in more detail the bases for its preemption defense in this regard, which is incorporated by reference.

5. Plaintiffs have failed to allege their fraud-based claims with the particularity required by Federal Rule of Civil Procedure 9(b). Defendant has previously filed a Motion to Dismiss setting out in more detail the bases for its preemption defense in this regard, which is incorporated by reference.

6. The product at issue was not dangerous when used in a reasonable and foreseeable manner and for its intended purpose.

7. Plaintiffs’ claims are barred to the extent the product was altered or modified in a manner that was not foreseeable. Plaintiffs are not, therefore, entitled to recover from Defendant in this action.

8. Plaintiff Sara Ali had full knowledge of, accepted, and/or assumed all risks and possible adverse effects related to the use of the LAP-BAND®, and her recovery is therefore

barred, diminished, reduced, or offset under the principles of assumption of the risk and/or informed consent.

9. Defendant pleads the sophisticated user and the learned intermediary defenses.

10. Plaintiffs have failed to join necessary or indispensable parties.

11. The injuries and/or damages alleged by Plaintiffs, if any, were the result of side effects that were unavoidable even though the product was properly prepared and was accompanied by proper directions or warnings.

12. The sole proximate cause of the injuries alleged by Plaintiffs may have been the actions, omissions, or negligence of a person or persons other than Defendant over which Defendant had no control and for whose actions, omissions, or negligence Defendant is in no way liable. Plaintiffs are not, therefore, entitled to recover from Defendant in this action.

13. To the extent that Plaintiffs receive or have received reimbursement or other compensation for all or part of their injuries and damages alleged in the Complaint, the amount of any damages that they may recover against Defendant must be diminished or apportioned in accordance with applicable state law, including the laws governing contribution and indemnity and/or the affirmative defenses of accord and satisfaction and payment and/or release and collateral sources, and Defendant will avail itself of such rights.

14. Defendant's conduct did not cause, proximately cause, solely cause, or solely proximately cause the injuries and/or damages claimed by Plaintiffs, if any.

15. Plaintiffs were not injured by Defendant's conduct and/or any product distributed by Defendant, and Defendant calls for strict proof thereof.

16. The injuries and/or damages alleged by Plaintiffs may have been caused by an independent, intervening, superseding action for which Defendant is in no way liable.

17. Plaintiffs' claims are barred because the alleged injuries are the result of an idiosyncratic reaction.

18. Discovery may show that Plaintiffs' damages, if any, are limited in whole or in part by their failure to mitigate.

19. At all relevant times, the product at issue was accompanied by proper directions for use, pursuant to generally recognized prevailing standards in existence at the time.

20. At all relevant times, the product at issue in this litigation was designed, manufactured, and marketed in accordance with applicable state of the art and state of the scientific knowledge.

21. Plaintiffs' claims against Defendant are barred by the statute of limitations and/or statute or rule of repose.

22. The claims alleged against Defendant, separately and severally, in the Complaint are barred by the Commerce Clause of the United States Constitution because they would, if allowed, impose an undue burden on interstate commerce.

23. The benefits of the product at issue in this litigation outweigh the risks, if any, which may be attendant to its administration to appropriate persons in accordance with applicable instructions and warnings.

24. Plaintiffs' Complaint is barred by the doctrines of laches, waiver and/or estoppel.

25. Defendant's conduct was not in any manner negligent or wanton or taken with deliberate disregard for the value of human life or safety.

26. Defendant denies that it participated in any act or omission to defraud, mislead, or fraudulently conceal information from consumers, medical professionals, Plaintiffs, or any other person or entity.

27. Defendant denies that it is liable for any punitive damages in this case.
28. Plaintiffs' request for punitive damages is subject to and limited by the limitation contained in Virginia Code § 8.01-38.1.
29. Any award of punitive damages cannot be sustained in this case if rendered by a jury that: (a) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damage award, taking into consideration the three constitutional guideposts of reprehensibility, ratio, and civil penalties, *see State Farm v. Campbell*, 538 U.S. 408 (2003); (b) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (c) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including without limitation Defendant's residence, wealth, and corporate status; (d) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (e) is not properly instructed regarding Plaintiffs' burden of proof beyond a reasonable doubt, or in the alternative, of clear and convincing evidence, with respect to each and every element of a claim for punitive damages; (f) is not instructed that it cannot award any punitive damages for the purpose of punishing Defendant for conduct outside of Virginia or for the purpose of changing its conduct outside of Virginia, *Philip Morris USA v. Williams*, 549 U.S. 346 (2007); (g) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionality adequate and objective standards, *e.g.*, consideration of the three constitutional guideposts of reprehensibility, ratio, and civil penalties, *see State Farm v.*

Campbell, 538 U.S. 408 (2003); and (h) is not required to render a unanimous verdict as to both liability for, and the amount of, punitive damages, would violate Defendant's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and by the Virginia Constitution and would be improper under the common law and public policies of the State of Virginia.

30. Plaintiffs' claims for punitive damages cannot be sustained to the extent an award of punitive damages under the laws of the United States and/or Virginia is not subject to a predetermined limit (such as a maximum multiple of compensatory damages or a maximum amount on the amount of punitive damages that a jury may impose), which would violate Defendant's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Virginia Constitution, would violate Defendant's right not to be subjected to an excessive award in violation of the Eighth Amendment to the United States Constitution and the Virginia Constitution, and would be improper under the common law and public policies of the State of Virginia.

31. Any award of punitive damages, which are penal in nature, rendered without providing Defendant the same protections that are accorded to criminal defendants—including the protection against unreasonable searches and seizures, self-incrimination, the right to confront witnesses, and a speedy trial—would violate Defendant's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and by the Virginia Constitution, and would be improper under the common law and the public policies of the State of Virginia.

32. Plaintiffs' claims for punitive damages cannot be sustained because Virginia law regarding the standards for determining liability for punitive damages failed to give Defendant

prior notice of the conduct for which punitive damages may be imposed and is void for vagueness in violation of Defendant's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Virginia Constitution, and would be improper under the common law and public policies of the State of Virginia.

33. Any award for punitive damages against Defendant in this matter would violate their guarantees of due process and protection against double jeopardy, excessive fines and multiple punishments under the Fifth, Eighth, and Fourteenth Amendments to the United States Constitution and under the Virginia Constitution, to the extent that Defendant might become subject to multiple punitive awards for the same alleged wrong or conduct. In addition, any such award would violate the Commerce Clause of the United States Constitution and principles of comity under the laws of Virginia.

34. Any claim of punitive damages against Defendant cannot be sustained, because any award of such damages would constitute a retroactive impairment of contractual obligations, in violation of the Contracts Clause of the United States Constitution, U.S. CONST., Art. I, § 10.

35. Defendant reserves the right to plead additional affirmative defenses as they become known in the course of discovery.

Dated: February 24, 2012

Respectfully submitted,

By: _____/s/

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Attorneys for Defendant Allergan USA, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the 24th day of February, 2012, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system.

And I hereby certify that I will mail the documents by U.S. mail to the following non-filing user:

Sybil Shainwald, Esq.
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200 West 57th Street
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/s/
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